



Christoph H. Röhrig, Ph.D.
Glycom A/S
Kogle Allé 4
2970 Hørsholm
DENMARK

Re: GRAS Notice No. GRN 000815

Dear Dr. Röhrig:

We are issuing a second revised copy of the response letter for GRN 000815. The original letter for this GRAS notice was signed on August 20, 2019. In an email dated January 15, 2020, Dr. Marta H. Mijs of Glycom A/S (Glycom) informed us of an omission in the discussion of the ingredient specifications in our letter. In her email, Dr. Mijs also informed us that the exposure estimates for the notified ingredient in infants were incorrectly reported in the notice. In an email dated February 5, 2020, we requested that Glycom submit a supplement stating the correct exposure estimates and discussing any related impact on the safety conclusion described in the notice. Glycom submitted a supplement on March 26, 2020. In response to the information about our omission, we included the specification for lactose on page 2, paragraph 3 of our letter. In response to the supplement, we corrected errors in the exposure estimates for the notified ingredient in infants on page 3, paragraph 1 of our letter. In a new footnote on page 4 of our letter, we included your statement that the corrected exposure estimates do not change your safety conclusion. This first revised response letter was signed on May 7, 2020.

In emails dated June 4, 2020 and June 17, 2020, Ms. Annette Lau of Glycom requested that we update the revised response letter to clarify the microbial limits when 2'-FL/DFL is used in liquid infant formulas that require a retort step. In a new footnote on page 2 of our letter, we included a statement noting that the limits for *Listeria monocytogenes* and *Cronobacter sakazakii*, were not needed and the limit for Enterobacteriaceae would be <10 CFU/g when 2'-FL/DFL is used in liquid infant formulas that require a retort step.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

If you have any questions, please contact me by electronic mail at Ellen.Anderson@fda.hhs.gov or by telephone at 240-402-1309.

Sincerely,

Ellen T.

Anderson -S

Digitally signed by Ellen
T. Anderson -S
Date: 2020.09.11
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Ellen Anderson
Division of Food Ingredients
Center for Food Safety
and Applied Nutrition